

6-24-81
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Memorandum

SUBJECT: PP# 9F2270 Chlorpyrifos in or on soybeans
Amendments of March 30, 1981 and May 4, 1981.

FROM: Elizabeth M. K. Leovey, Ph.D., Chemist
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TO: Jay Ellenberger, Product Manager No. 12
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THRU: Charles Trichilo, Chief
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The following deficiencies (summarized) were left to be resolved from the previous amendment (memo: E.M.K. Leovey, 12/23/80).

1. A minimum time period between applications of Lorsban 4E should be indicated on the label.
2. The nature of the plant residue has not been adequately delineated.
3. A goat metabolism study using radiolabelled chlorpyrifos is needed to further clarify the metabolism of chlorpyrifos in animals.
4. Additional residue data on soybeans are needed from the major soybean producing states. These data should cover the maximum proposed use and the granular formulation.
5. A processing study is needed reflecting residues at tolerance level.
6. We are withholding judgment on the proposed increases in tolerance for meat, fat, and meat by-products of goats and sheep until the above deficiencies have been resolved.

Our comments to the petitioner's response to the above questions follow.

Response to 1

The petitioner has revised the label with "Do not apply last treatment within 28 days before harvest nor apply last two treatments closer than 14 days apart." The deficiency is resolved.

Response to 2 and 3

Metabolism studies of chlorpyrifos in goats, apples and soybeans were submitted with PP# OP2281, chlorpyrifos in or on alfalfa, amendment of March 4, 1981. In our review of that submission, we deferred to TOX on the significance of apple metabolites B, C, D and E and the unidentified apple and soybean metabolites, particularly the water soluble metabolites.

We also concluded that the residues of concern from the feeding of chlorpyrifos to goats were the parent chlorpyrifos and its metabolite 3,5,6-trichloro-2 pyridinol (TCP). We will withhold a conclusion on the secondary residues resulting from this use pending a response from TOX on PP# OP2281. If additional plant metabolites are in need of regulation, then further animal metabolism studies may be needed for these compounds.

Response to 4

In lieu of submitting additional residue data reflecting the maximum application rate, the petitioner has lowered the application rate from a total of 5 lbs. down to 3 lbs. act./A./season, has imposed a 14-day interval between the last two treatments (see #1 above) and has imposed a restriction against making applications in less than 10 gals. of water per acre for ground application. The question regarding the use of the granular formulation was not addressed by the petitioner.

There is a feeding restriction against the use of soybean forage and hay. The item(s) for concern here are soybeans and soybean processing fractions.

The highest bean residue values reported were from a North Carolina study using a ground application rate of 3 gals./A. The highest residue value reported was 0.82 ppm. The petitioner has revised his use directions to prohibit applications with less than 10 gallons per acre. The remaining studies show combined residues < 0.2 ppm. These studies reflect foliar application.

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We have re-evaluated our question regarding the granular formulation. Application is to be at planting or post-emergence in a band and incorporated. Such a treatment would be early in the soybean growing season. Residues from that use would be minor compared to those resulting from the foliar uses. We are not raising any further questions on the use of the granular formulation.

Based on the revisions in the use pattern as discussed above, we conclude that residues in soybeans will not exceed 1 ppm. In fact, a tolerance of 0.5 ppm would be more appropriate for soybeans.

Our conclusions regarding an appropriate soybean tolerance is based on the assumption that the only regulable residues will be chlorpyrifos and TCP. If other residues are found to be in need of regulation (see above our deferral to TOX), then additional residue data and a higher tolerance may be needed.

Response to 5

In the metabolism study for soybeans containing 0.5 ppm ^{14}C residues equivalent to chlorpyrifos, hexane was used to strip oil from the soybean. From 100 gm of beans, 17.3 gm of crude oil was obtained containing 0.436 ppm chlorpyrifos equivalents. By difference, the meal would contain 0.51 ppm (W.R. Bauriedil, Dow Chemical, 5/6/81). Only a small portion of the residue, at most 16%, was chlorpyrifos and TCP. These data were generated with chlorpyrifos-treated beans and reflect a 52-day PHI. At that PHI, residues would be TCP or residues more polar than TCP in nature. These residues would be expected to be present in the meal rather than the oil. The soybean fraction study with unlabeled chlorpyrifos which was discussed in our April 29, 1980, review shows that chlorpyrifos and TCP residues occur primarily in hulls and meal but were less than the residue in the bean. Considering the processing study, the bean metabolism work and the lower tolerance we have suggested, we conclude that residues in the processed fractions will not exceed the tolerance suggested by us. This deficiency is resolved provided additional metabolites are not judged in need of regulation.

Response to 6

We have recently reviewed an amendment to PP# OF2281, chlorpyrifos on alfalfa forage at 4 ppm and alfalfa hay at 15 ppm. Based on that evaluation of data, we have concluded that higher tolerances are needed for meat, milk, poultry and eggs.

The 1 ppm soybean tolerance proposed in this petition (or the 0.5 ppm level we suggested) will not contribute as much chlorpyrifos residue to the diet of livestock as the alfalfa proposal in PP# OF2281 will. The proposed soybean use will not result in secondary residues in meat, fat and meat byproducts of cattle, hogs and horses exceeding the established tolerances for these commodities. The proposed goat and sheep tolerances also appear adequate to cover residues in the meat, fat and meat byproducts of these animals. The established milk, poultry tissue and egg tolerances are also adequate to cover secondary residues resulting in these commodities from the proposed use.

Conclusions and Recommendations

1. We have deferred to TOX on the need to identify apple metabolites B, C, D and E and the unidentified apple and soybean metabolites, particularly the water soluble metabolites (see also our review of OF2281).
2. Provided chlorpyrifos and TCP are concluded to be the only residues of concern, residues in soybeans are not expected to exceed 0.5 ppm. A 0.5 ppm tolerance should be proposed. If TOX concludes that other residues are of concern, then additional residue data and a higher tolerance may be needed.
3. Residues of chlorpyrifos and TCP in soybean processing fractions are not expected to exceed the level in the bean. A food/feed additive tolerance is not needed.
- 4a. The established tolerances for milk, eggs and for the meat, fat and meat byproducts of cattle, hogs, horses and poultry are adequate to cover secondary residues of chlorpyrifos and TCP resulting in these commodities from the proposed use.
- b. The proposed goat and sheep tolerances are also adequate to cover secondary residues resulting from the proposed use.

We recommend against the proposed tolerances for the reasons cited in conclusions 1 and 2 above. Resolution of these will be needed before we can recommend favorably for the proposed tolerances.

cc: R.F., Circ. (3), Leovey, Watts, FDA, TOX, EEB, EFB, PP# 9F2270

RDI: Quick, 6/19/81: Schmitt, 6/22/81

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RCR:Stoutamire:DCR#34169:WANG#0696A:Raven:pjb:5/28/81